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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,304	11/08/2001	Timothy Ringeisen	KN P 0020	5717

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KENSEY NASH CORPORATION
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EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
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1618

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01/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/010,304	Applicant(s) RINGEISEN, TIMOTHY	
	Examiner Eric E. Silverman, PhD	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 14, 18-23 and 33-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10, 14, 18-23 and 33-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/2007 has been entered.

Claims 6 – 10, 14, 28, and 33 – 51 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33 36, 39 – 43, 45, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Applicant has not pointed to where support for the newly claimed subject matter lies in the original disclosure. A careful review of the originally filed disclosure reveals no support for these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). **In the present instance, claims 10 and 44** recite the broad recitation biologic modifiers, and the claims also recite drugs, hydroxyapatites, antithromogenic agents, etc. which are the narrower statements of the range/limitation.

Note that these claims also recite other broad/narrow statements of limitations, for example, the recitation of "cellular components" (broad) and "proteins" (narrow), "viruses" (broad) and "proteins" (narrow), "proteins" (broad) and "hormones" (partially overlapping with protein), etc.

Claims 6 – 10, 14, and 28, and 33 – 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 6 – 9, 14 and 28 have been amended to recite that the entire volume of the solution becomes (or is transformed into or thickens into) a gel. It is not clear what "volume" is being referred to. When a solution gels, its volume typically changes - the volume may either increase or decrease depending on the nature of the solvent and the polymer. In the case where the volume increases, does this limitation mean that only the volume equal to that of the original solution becomes a gel, and the rest remains a solution? Or does it mean something else? In cases where the volume decreases, it is not clear how it would be possible for the "entire volume of the solution" to be a gel if the resulting gel has less volume than the original solution. Further, since there is no requirement that the second solvent be soluble in the first, it is not clear what is in the solution that is gelling. Is the second solvent required to be part of the solution, or not?

The remaining claims are rejected for ultimately depending on one of the independent claims without clarifying this issue, thereby incorporating the indefiniteness of the independent claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 10, 23, 24, 28 and 41 – 51 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,077,049 to Dunn et al. The rejection of claims 8, 10, 23, and 24 is **maintained** for reasons of record and those discussed below.

1. The amendment to claim 8.

The substantial change to claim 8 is that part (f) now requires that the "entire volume of solution has transformed to a transparent gel." This limitation is a indefinite and unclear for the reasons discussed above, in the rejections under the second paragraph of 35 U.S.C. 112. One possible interpretation of the claim follows. The term "the solution" in part (f) finds antecedent basis in part (d) of the claim, and refers to the mixture of first solvent and polymer. The second solvent is not necessarily part of the solution, as it is added to the solution and need not dissolve therein (there being no requirement that the first and second solvents be miscible or even soluble in one another). Accordingly, there is no requirement in the claim that the second solvent be part of the gel or be incorporated into the gel. Considering the indefinite nature of the claim, and this analysis the teachings of Dunn, as discussed in the office actions mailed 1/13/2006 and 6/11/2007 are deemed to meet the new limitation of claim 8. In Dunn, the although all of the second solution may or may not be incorporated into the final gel (see Examples), the limitation of the claim is nonetheless met.

2. Claim 28

Note that the office action mailed 1/13/2006 stated that Dunn did not anticipate claim 28 because "Dunn does not teach the use of THF to dissolve the polymer," (page 5), and thus the Dunn reference was applied as part of a rejection under 35 USC

103(a) in that action. Upon review, this statement appears to have been an inaccurate reading of Dunn. Dunn teaches the use of THF (tetrahydrofuran) at col. 5, lines 7 - 51.

2. The new claims.

The "spreading or injecting the gel over a three dimensional object and removing the three-dimensional object after removing the first and second solvent from the gel" of claim 41 is met by Dunn at example 1, where Dunn puts the gel in a container (a 3-dimensional object) and later removes the gel from the container (which is the same as removing the container from the gel). Adding the biologically active agent by mixing with the polymer and first solvent prior to addition of the second solvent" of claim 42 is taught by Dunn in the examples. The biologically active agent is understood to be inherently in the pores of the polymeric body in Dunn, as per claim 43. As previously discussed, Dunn teaches at least the growth hormones of claim 44 beginning at col. 4, line 51. Placing the gel in contact with a separate body leaving it bound to the body, as in claim 45, reads on Dunn's teaching of injecting the gel into a body leaving it attached to the tissue, at col. 8, lines 20 - 40. Dunn teaches polyurethanes of claim 46, tetrahydrofuran(THF) of claims 47 and 50, dimethyl sulfoxide (DMS) of claimd 48 and 51, and lactic acid polymers (lactides) at col. 5, lines 7 - 51.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that Dunn does not teach the new limitation that "entire volume of solution has transformed to a transparent gel." For the reasons discussed above this limitation, although indefinite, is taught by Dunn as it is best understood.

Claims 6, 7, 9, 10, 18 – 23 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,492,154 to Einstman et al. in view of US 5,447,724 t Helmus et al. and US 4,769,286 to Le Noane et al. for reasons of record and those discussed below.

With regard to the new claims, the biological materials taught by Einstman at col. 1, lines 37 - 41 meet the claimed "biodegradable" other material of 33, as do the biologically active agents of Helmus (abstract). The fibers, beads and rings of La Noane (abstract, claims) meet the reinforcement materials and prosthesis of claims 34 - 36. The biologically active agents of Helmus meet the "biologic modifiers" and "physiologically acceptable drugs" of claim 38. The teaching to use the gel as a component of beads and rings, in La Noane, meets the requirements of claims 39 and 40.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants argue that the references do not teach the entire volume of the solvent becoming a gel, as claimed. Rather, Applicant avers that Einstman teaches lowering the temperature to form a gel. In response, it is noted that in addition to teaching using temperature to control gel formation, Einstman also teaches adding a solvent to induce gelling. Col 5, lines 40 - 65. Note that the amount of non-solvent used to induce gellation is less than that which is required to cause the composition to gel at the temperature at which the solvent is added. Einstman then cools the solution to finally cause the gel to form (col. 5, line 65 - col. 6). While the claims do not require a cooling

step, instant comprising language does not exclude such a step. Because the amount of non-solvent (second solvent) used by Einstman is less than that which is required to cause gelation, it is understood that the entire volume will gel, within the meaning of the claim (note that this limitation is indefinite as discussed above, and so it is not clear what is actually required to meet the limitation).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'E. Silverman', with a long horizontal flourish extending to the right.

Eric E. Silverman, PhD
Art Unit 1618